

### REMARKS

The Application has been reviewed in light of the Office Action mailed August 13, 2003. At the time of the Office Action, Claims 1, 2, 7, 11, and 12 were pending in this Application. Claims 3-6 and 8-10 were previously cancelled by Applicant without prejudice or disclaimer. Claims 1, 2, 7, 11, and 12 were rejected.

#### **Rejections Under 35 U.S.C. §103**

Claims 1-2, 7 and 11 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,287,516 issued to James R. Matson et al. (hereinafter "Matson") in view of U.S. Patent No. 5, 919,444 issued to James G. Norman, Jr. (hereinafter "Norman"). Applicant respectfully traverses and submits that there is no motivation to combine these references.

Multiple references or activities classified as prior art under 35 U.S.C. § 102(b) may be combined under § 103 to bar patentability based on obviousness in light of that combination. *Labounty Mfg., Inc. v. United States ITC*, 958 F.2d 1066, 1071 (Fed. Cir. 1992); *In re Corcoran*, 640 F.2d 1331, 1333 (C.C.P.A. 1981). When considering a combination of prior art references for determining obviousness, there must be some teaching, suggestion, or motivation to combine the references. *Rouffet*, 149 F.3d at 1355. "Although the suggestion to combine references may flow from the nature of the problem, it more often comes from the teachings of the pertinent references, or from the ordinary knowledge of those skilled in the art that certain references are of special importance in a particular field." *Id.* at 1355-65. Hence, where the claimed invention combines two known elements, "the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." *See In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992) (quoting *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984)); *Rouffet*, 149 F.3d at 1356. However, as stated above, "[t]he suggestion to combine [two references] may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved." *WMS Gaming Inc. v. International Game Technology*, 184 F.3d 1339, 1355 (Fed. Cir. 1999).

In determining whether a claimed invention is obvious in light of a combination of references, the court must be vigilant not to allow hindsight to cloud the question. *McGinley*, 262 F.3d at 1351 (citing *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997)). To prevent such "hindsight invalidation," courts require that there be some teaching, suggestion, or reason to combine cited references that are alleged to render the patent claim obvious. *McGinley*, 262 F.3d at 1351. Whether such a motivation to combine prior art references has been demonstrated is a question of fact. *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348 (Fed. Cir.), *cert. denied*, 530 U.S. 1238 (2000).

Specifically, Matson does not provide a teaching, suggestion or reason to combine the reference with Norman and Norman does not provide a teaching, suggestion or reason to combine with Matson. The Examiner argues that Matson "teach a hemofiltration method and system ... to remove selective inflammatory mediators including cytokines, prostaglandins, TNF, IL-1 eta from blood...." The Examiner asserts that Norman "teaches that IL-1 block can be administered in combination with other drugs such as prostaglandin inhibitors ... to inhibit IL-1 production." The Examiner goes on to state that "Claims 1-2, 7 and 11 essentially differ from the hemofiltration system and method of Matson et al. in reciting the provision of [a] therapeutic agent selected from the group consisting of allopurinol, elastase inhibitors and prostaglandin inhibitors."

For the purposes of the present response, we assume that the Examiner's assertions quoted above are correct. Even assuming these assertions are correct, they in no way indicate a teaching or suggestion to combine a hemofiltration system with an IL-1 blocking compound. The Examiner admits that the present claims differ from Matson in they recite addition of a therapeutic agent. Matson therefore, admittedly lacks the addition of such an agent. Furthermore, Matson appears to rely solely upon the usefulness of the hemofilter disclosed and does not teach or suggest adding anything to the blood.

Similarly, Norman teaches administering an IL-1 blocking agent to a patient. Methods of administration are described in Col. 7, Line 56 - Col. 8, Line 7. None of these methods normally involve or are combined with methodologies that also remove a component from the patient's blood, as described in Matson. Therefore, the methods of administration of Norman do not teach or suggest the combination of the IL-1 blocking agent

described therein with the hemofilters of Matson. Norman also fails to contain any other information that would suggest such a combination.

Furthermore, Applicant submits that there is no other motivation to combine the references. Rather, the Examiner appears to be engaging in impermissible hindsight. Applicants have combined use of a hemofilter with the addition of a therapeutic agent. Applicants have shown that this combination is useful. Now the Examiner has used Applicants' finding to assert that that there was a pre-existing motivation to combine a hemofilter with a therapeutic agent as claimed.

In addition, the Examiner must evaluate secondary considerations. The objective considerations of nonobviousness include, among others, "copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention." *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998).

"While secondary considerations must be considered and may be extremely probative evidence of nonobviousness, they do not control the obviousness conclusion." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 664 (Fed. Cir. 2000). However, a very strong case of obviousness based on the teaching of the prior art is required to completely overpower secondary considerations. *Newell Cox. v. Kenney Mfg. Co.*, 864 F.2d 757, 769 (Fed. Cir. 1988).

Although multiple secondary considerations may apply to the present invention, Applicant wishes to focus on one consideration in the present response. Specifically, Applicant notes that both Matson and Norman, as well as the present application spend a great deal of their backgrounds discussing serious diseases that are difficult to treat. This certainly constitutes a long felt, but unsolved need. Given the advantages of combining a hemofilter with a therapeutic agent to meet this need, it seems highly unlikely that such a combination would not have been specifically invented and disclosed prior to Applicant's patent application if the combination is in fact obvious in light of Norman and Matson. The absence of any such prior combination in the presence of such a great need strongly indicates that the combination is not obvious.

The absence of any teaching or suggestion to combine Norman and Matson coupled with the presence of a secondary consideration strongly in Applicant's favor indicates that there is no motivation to combine Norman and Matson and that Claims 1-2, 7 and 11 are not obvious in light of the two references.

Claim 12 was rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over Matson in view of Norman and U.S. Patent No. 6,008,199 issued to Brian William Grinnell et al. (hereinafter "Grinnell"). Applicant respectfully traverses and submits that, for reasons described above, there is not motivation to combine Matson and Norman. Furthermore, there is no motivation to combine Grinnell with Matson for reasons set forth in Applicant's previous response. Specifically, Grinnell, like Norman, merely describes administration of a therapeutic agent to a patient. Nothing in Grinnell teaches or suggests combining its therapeutic agent with a hemofilter. Furthermore, as noted above, given the long felt need for new treatments, if such a combination were obvious, it would likely have been made prior to the present invention. Therefore, Applicants submit that Claim 12 is not obvious in light of Matson, Norman and Grinnell.

Claims 1-2, 7 and 11 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,193,681 issued to Alan Davidner et al. (hereinafter "Davidner") in view of Norman. Applicant respectfully traverses and submits that there is no motivation to combine Davidner with Norman. Specifically, the Examiner describes Davidner in nearly identical language to Matson. Therefore, all of the above reasoning relating to the combination of Matson and Norman also applies to the combination of Davidner and Norman. Specifically, Davidner does not teach or suggest the combination of a hemofilter and a therapeutic agent such as those described in Norman. Additionally, there is a long felt but unsolved need that is met by the present invention, indicating that if the invention were in fact obvious, it would have been made prior to Applicant's invention thereof. Accordingly, Applicant submits that Claims 1-2, 7 and 11 are not obvious in light of Davidner and Matson.

Claim 12 was rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Davidner in view of Norman and Grinnell. Applicant respectfully traverses and submits that there is no motivation to combine Davidner and Norman as set forth above. Furthermore, Grinnell, fails to teach or suggest any mode of administration of

its therapeutic agent that is coupled with hemodialysis. Furthermore, given the long felt, but unsolved need described above, it is unlikely that hemodialysis coupled with a therapeutic agent of Norman or Grinnell would not have been previously invented if it were obvious.

Claim 12 has been amended to better define the scope of Applicant's invention.

Therefore Applicants assert that Claim 12 amended is not obvious in light of Davidner, Norman and Grinnell.

**Application of 35 U.S.C. §103(c)**

Applicants further note that Matson may not be used as a reference for a §103(a) rejection of the present Application under the law set forth in §103(c). Matson was not issued or published as of the filing date of the present application. Therefore, Matson is only available as a reference through the criteria set forth in §§102 (e), (f) or (g). Under §103(c) such references may not be used in an obviousness rejection if the reference and the present application were commonly owned or subject to a common assignment obligation at the time of invention of the invention in the present application. At the time of invention of the invention in the present application, the inventors were under a duty to assign all rights in the invention to Immunocept, L.L.C. or its predecessor in interest, Bioscience Research Associates. At the same time Matson was under an obligation to assign all rights in that application (now an issued patent) to the same entity. Therefore, Matson may not be used as a reference under §103(a) against the present application.

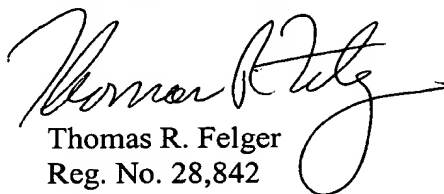
**CONCLUSION**

For the foregoing reasons, Applicant requests that Claims 1, 2, 7, 11 and 12 as amended be allowed. Early and favorable acceptance of this Application is respectfully requested.

Applicant believes no fees are due at this time, however, the Commissioner is hereby authorized to charge any fee to Deposit Account No. 50-2148 of BAKER BOTTS L.L.P. in order to effectuate this filing.

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